

75. (New) A composition comprising an immunostimulant and an isolated polypeptide comprising amino acids 1-39 of SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

76. (New) The composition according to claim 72, wherein the polypeptide has at least 95% identity to the entirety of SEQ ID NO: 525.

77. (New) The composition according to any one of claims 72-76, wherein the immunostimulant is selected from the group consisting of a monophosphoryl lipid A, a CpG-containing oligonucleotide, a saponin, or a combination thereof.

78. (New) The composition according to any one of claims 72-76, wherein the immunostimulant is selected from the group consisting of 3D-MPL, QS21, or a combination thereof.

79. (New) The composition according to any one of claims 72-76, wherein the immunostimulant comprises 3D-MPL, QS21 and tocopherol in an oil-in-water emulsion.

REMARKS

Favorable reconsideration of the instant application in view of the present amendment and the following comments is respectfully requested. Claims 21-22 and 65-72 are under examination in this application. Claim 72 has been amended and claims 66-71 have been cancelled. Claims 73-79 are newly added. Support for the above amendment can be found throughout the specification, for example, at page 36, line 10; page 4, lines 20-25; page 45, line 26; page 45, line 26 to page 47, line 12, and elsewhere. In addition, the specification has been amended, as suggested by the Examiner, by updating the CROSS REFERENCE TO RELATED APPLICATIONS. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants acknowledge the objection to the drawings by the Draftsperson as set forth on Form PTO-948. Corrected drawings are attached herewith. Regarding the Information Disclosure Statement, the Examiner alleges that references BL, BM and DJ recite Accession Numbers which could not be located in the National Center for Biotechnology Information (NCBI) database or in the Derwent sequence database. Copies of DJ, BL and BM are enclosed herewith for the Examiner's convenience.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 21, 66, 69 and 71-72 under 35 U.S.C. § 102(b) as anticipated by Bandman *et al.* (U.S. 5,786,148). The Examiner alleges that Bandman *et al.* teach a HPSK protein sequence 88.8% identical to SEQ ID NO: 525 of the instant application. The Examiner further alleges that Bandman *et al.* teach that the protein sequence disclosed therein may be combined with adjuvants, physiological carriers or be used to produce antibodies.

Applicants respectfully traverse this rejection. The presently pending claims are drawn to isolated polypeptides having at least 90% identity to the entirety of SEQ ID NO: 525 and isolated polypeptide having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ ID NO: 525; wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as it is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Moreover, the elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). See also MPEP 2131.

Applicants submit that Bandman *et al.* does not anticipate the polypeptides currently claimed by the applicants. More particularly, Bandman *et al.*, while disclosing a sequence having some degree of similarity to SEQ ID NO: 525, does not disclose a sequence having at least 90% identity to the entirety of SEQ ID NO: 525, as currently claimed, much less that the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

Applicants further submit that amino acids 1-39 of SEQ ID NO: 525 are unique to SEQ ID NO: 525, and thus are not contained in the polypeptide disclosed by Bandman *et al.* Consequently, Bandman *et al.* fails to anticipate the subject matter of new claims 73 and 75, drawn to isolated polypeptides comprising amino acid residues 1-39 of SEQ ID NO: 525. Accordingly, in view of the above amendment and remarks, applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 102(b).

The Examiner also rejects claims 21, 66-69 and 71-72 under 35 U.S.C. § 102(e) as anticipated by Gimeno *et al.* (U.S. 5,955,306). In particular the Examiner alleges that Gimeno *et al.* teach a protein that is 97.6% identical to SEQ ID NO:525 of the instant application. The Examiner further alleges that Gimeno *et al.* teach that immunogenic proteins may be mixed with adjuvants and/or formulated in physiological acceptable carriers.

Applicants respectfully traverse this rejection. As noted above, the currently claimed invention is drawn to isolated polypeptides having at least 90% identity to the entirety of SEQ ID NO: 525; and isolated polypeptides having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ ID NO: 525. Applicants submit that Gimeno *et al.*, while describing a sequence having some degree of similarity with the polypeptide of SEQ ID NO: 525, does not specifically describe in complete detail the polypeptides as currently claimed by the applicants, much less that the polypeptides contain an amino acid sequence capable of stimulating human T-cells. Accordingly, the instant claims, as amended hereinabove, are indeed novel over Gimeno *et al.* Reconsideration and withdrawal of the Examiner's rejection are thus respectfully requested.

Rejection under 35 U.S.C. § 103

The Examiner rejects claims 21-22, 66, 69 and 71-72 under 35 U.S.C. § 103(a) as unpatentable over Bandman *et al.* in view of Hauser *et al.* (U.S. 5,776,468), and over Gimeno *et al.* in view of Hauser *et al.* (U.S. 5,776,468). In particular the Examiner alleges that Bandman *et al.* and Gimeno *et al.* teach the polypeptide according to the instant application and that Hauser *et al.* provides an immunostimulant which induces a type I response.

As noted above, neither Bandman *et al.* nor Gimeno *et al.* teach the currently claimed polypeptides related to SEQ ID NO: 525. Moreover, the deficiencies of Bandman *et al.*

and Gimeno *et al.* are not remedied by Houser *et al.*, which merely discloses an immunostimulant, but does not disclose a polypeptide presently claimed by Applicants. Accordingly, Applicants submit that neither Bandman *et al.*, nor Gimeno *et al.*, alone or in combination with Hauser *et al.*, would lead the skilled artisan to any expectation of arriving at the Applicants' claimed invention when the combined disclosures of these references simply do not teach each and every element currently claimed. Applicants respectfully request that this rejection under 35 U.S.C. § 103(a) be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current Amendment, the first page of which is captioned "Version with Markings to Show Changes Made."

Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the undersigned at (206) 694-4885 with any questions, comments and/or suggestions relating to this communication. Please credit any overpayment or charge any deficiency to Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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Enclosure:

Postcard

14 Sheets Drawings (Figs. 1-12B)

3 References

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please replace the paragraph on page 1, under the heading "CROSS REFERENCE TO RELATED APPLICATIONS" with the following rewritten paragraph.

--This application is a continuation-in-part of U.S. Patent Application No. 09/443,686, filed November 18, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/352,616, filed July 13, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/288,946, filed April 9, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/232,149, filed January 15, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/159,812, filed September 23, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/115,453, filed July 14, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/030,607, filed February 25, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/020,956, filed February 9, 1998, which is a continuation-in-part of U.S. Patent Application No. 08/904,804, filed August 1, 1997, which is a continuation-in-part of U.S. Patent Application No. 08/806,099, filed February 25, 1997.--

In the Claims:

Claims 66-71 have been canceled, claim 72 has been amended and claims 73-79 are newly added.

72. (Amended) A composition comprising an immunostimulant and an isolated polypeptide having at least 90% identity to the entirety of SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells. ~~according to any one of claims 65-70.~~

73. (New) A composition comprising an immunostimulant and an isolated polypeptide having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ

ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

74. (New) A composition comprising an immunostimulant and an isolated polypeptide comprising SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

75. (New) A composition comprising an immunostimulant and an isolated polypeptide comprising amino acids 1-39 of SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

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